AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 8

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00002	See Block 16C		

6. ISSUED BY CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

7. ADMINISTERED BY *(If other than Item 6)* CODE ASPR-BARDA

ASPR-BARDA
US DEPT OF HEALTH & HUMAN SERVICES
BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT
200 INDEPENDENCE AVE, S.W.
Washington DC 20201

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

DIASORIN INC. 334234
DIASORIN INC.
1951 NORTHWESTERN AVE
STILLWATER MN 550827536

CODE 334234 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00070

10B. DATED *(SEE ITEM 13)* 04/10/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted , such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)* Net Decrease: -$55,045.00
2020.199COV3.25106

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE

X A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
FAR 52.243-1 Alt. V - Changes - Fixed Price (Apr 1984)

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 41-1980846
DUNS Number: 033429783
A) In accordance with FAR 52.243-1 Alt. V Changes - Fixed Price (Apr 1984), the purpose of this modification is to make the following changes to the contract:

1. Revise "Attachment 1 - Statement of Work" and "Attachment 3 - Schedule of Payments" to remove Deliverable #3 language.
2. De-obligate funding for Deliverable #3 in the amount of $55,045.

B) This is a bilateral modification. The total dollar amount of all CLINs that are currently being performed under the contract has been modified to reflect mutually agreed

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
JOHN C. WALTER, PRESIDENT		TROY G. FRANCIS	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED 11/3/2020	16B. UNITED STATES OF AMERICA *(Signature of Contracting Officer)* Troy G. Francis -S Digitally signed by Troy G. Francis -S DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=2001931480, cn=Troy G. Francis -S Date: 2020.11.02 17:57:38 -05'00'	16C. DATE SIGNED 11/2/2020

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

NAME OF OFFEROR OR CONTRACTOR
DIASORIN INC. 334234

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	upon changes within the scope of the contract. The parties bilaterally agree to the changes in the terms and conditions of the contract. All other terms and conditions of the contract remain unchanged. Appr. Yr.: 2020 CAN: 199COV3 Object Class: 25106 Period of Performance: 04/13/2020 to 08/31/2020 Change Item 1 to read as follows(amount shown is the obligated amount):				
1	ASPR-20-01674 -- DiaSorin LIAISON SARS-CoV-2 S1/S2 IgG Obligated Amount: -$55,045.00				-55,045.00

Attachment 1

Biomedical Advanced Research and Development Authority (BARDA)
Broad Agency Announcement BAA-20-100-SOL-0002

LIAISON SARS-CoV-2 S1/S2 IgG
Area of Interest #4 (COVID-19)

Statement of Work (SOW)

PREAMBLE

Independently, and not as an agent of the government, the contractor shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this contract, as needed to perform the tasks set forth below.

The government reserves the right to modify the budget, progress, schedule, or milestones to add or delete processes, schedules, or deliverables if the need arises. Because of the nature of this contract and the complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected or removed, or whether schedule or budget adjustments should be made. The government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

Overall Objectives and Scope

The overall objective of this contract is to validate, market, and obtain regulatory authorization in the United States and worldwide for a fully automated, chemiluminescent immunoassay for the qualitative detection of IgG class antibodies against the SARS-CoV-2 virus in human sera. This assay is intended as an aid to determining patient exposure and the presence of neutralizing antibodies regarding SARS-COV-2 virus and COVID-19 disease.

The scope of work for this contract includes all professional, scientific, manufacturing and support expertise and labor to accomplish the above overall objective. The scope will include clinical sample collection, manufacturing transfer and procedures to produce assay validation lots, and analytical and clinical validation of those lots. Lastly, EUA submissions to FDA will be made with the goal of obtaining Emergency Use Authorization of the assay. Use of the final product in the US will be limited to those CLIA certified laboratories utilizing the LIAISON XL automated instrument platform.

The effort for LIAISON SARS-CoV-2 S1/S2 IgG will progress in work segments with key Deliverables being due during the Base Period of performance of the contract (the Base Period will be labeled Contract Line Item Number (CLIN) 0001). Each Deliverable will require a concrete work segment with a well-defined objective, scope of work, and success metric for accomplishing the Deliverable. The work segments for each Deliverable may occur sequentially or simultaneously based on the pathway and needs of the project.

In addition to the requirements outlined under "Section F.2 Deliverables" of the contract, the following deliverables are defined for this project:

1. **Deliverable 1** – Project Plan
2. **Deliverable 2** – EUA submission to the FDA
3. ~~**Deliverable 3** – EUA amendment for expanded claim~~
4. **Deliverable 4** – EUA submission to FDA for IgM assay
5. **Deliverable 5** – Final Report and Final Data Package

Deliverable 1: Project Plan

Objective:
Provide a detailed project plan outlining the goals, deliverables, and intended pathway for the project.

Scope of Work:
- Create a Gantt Chart that identifies all goals and deliverables for the project
- Create a resource tracking document
- Provide a description of the tools/techniques used to track and monitor the cost and schedule
- Provide a Risk Management Plan for the entire project

Success Metric for Completion of Deliverable 1:
Provide Project Plan and Gantt Chart, that is received and approved by the Contracting Officer (CO) and Contracting Officer's Representative (COR), within 10 days of contract award.

Deliverable 2: EUA Submission to FDA

Objective:
Complete and Submit EUA documentation to the US FDA

Scope of Work:
- Complete EUA documentation per most recent FDA EUA template, to include
  - Validation testing results as describe in FDA document "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency" and/or FDA communication to DiaSorin.
  - Complete Device Description
  - Any other information as requested in the EUA template or instructions
- Submit EUA to US FDA for a claim of detection of IgG antibodies against SARS-CoV-2. Note that as of March 31, 2020, FDA has communicated to DiaSorin to forego the pre-EUA process and proceed directly to EUA submission.
- Receive confirmation of receipt from FDA

Success Metric for Completion of Deliverable 2:
Provide Copy of EUA submission to BARDA along with FDA confirmation of receipt

~~**Deliverable 3: EUA Amendment to FDA for expanded claim**~~

~~**Objective:**~~
~~Complete and Submit EUA amendment documentation to the US FDA~~

~~**Scope of Work:**~~
- ~~Complete EUA amendment documentation per most recent FDA EUA template, to include~~
  - ~~Validation testing results to support a semiquantitative use of the LIAISON IgG test results for SARS-CoV-2~~
- ~~Submit EUA amendment to US FDA~~
- ~~Receive confirmation of receipt from FDA~~

~~**Success Metric for Completion of Deliverable 3:**~~
~~Provide Copy of EUA amendment submission to BARDA along with FDA confirmation of receipt~~

Deliverable 4: EUA Submission to FDA for IgM assay

Objective:
Complete and Submit EUA documentation to the US FDA for a SARS CoV 2 IgM serology assay

Scope of Work:

- Complete EUA documentation per most recent FDA EUA template, to include
  - Validation testing results as describe in FDA document "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency" and/or FDA communication to DiaSorin.
  - Complete Device Description
  - Any other information as requested in the EUA template or instructions
- Submit EUA to US FDA for a claim of detection of IgM antibodies against SARS-CoV-2.
- Receive confirmation of receipt from FDA

Success Metric for Completion of Deliverable 2:
Provide Copy of EUA IgM submission to BARDA along with FDA confirmation of receipt

Deliverable 5: Final Report and Final Data Package

Objective:
Complete and deliver all outstanding documentation and data to BARDA.

Scope of Work:

- Complete final study report and documentation including financial budget

Success Metric for Completion of Deliverable 4:
Submission of all documentation and data (in a non-proprietary format) in accordance with Section F of the contract, at or prior to the close of the project

PROGRAM MANAGEMENT

The contractor shall provide the following as outlined below:

a) The overall management, integration, and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;

b) A Principal Investigator (PI) or Project Manager (PM) responsible for project management, communication, tracking, monitoring, and reporting on status, progress, and modifications to the project requirements, deliverables and timelines, including projects undertaken by subcontractors;

c) A PM with responsibility for monitoring and tracking day-to-day progress and timelines of deliverables, coordinating communication and project activities, costs incurred, and program management.

d) A BARDA liaison (maybe be the PM) with responsibility for effective communication with the Contracting Officer (CO), Contract Specialist (CS), and Contracting Officer's Representative (COR);

e) Administrative and legal staff capable of developing compliant subcontracts, consulting, and other legal agreements, while also ensuring timely acquisition of all proprietary rights, including intellectual property (IP) rights and reporting all inventions made in the performance of the contract;

f) Administrative staff capable of financial management and reporting on all activities conducted by the contractor and any subcontractors;

g) Contract Review Meetings

The contractor shall participate in regular meetings to coordinate and oversee the contract effort conjointly with the CO, CS, and COR. Such meetings may include, but are not limited to, the following:

- Meeting with the contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale-up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues.

- Meeting with individual contractors and other government officials to discuss the technical, regulatory, and ethical aspects of the program.

- Meeting with technical consultants to discuss technical data provided by the contractor.

h) The contractor shall participate in teleconferences, daily to twice monthly, with the CO, CS and COR to discuss the performance of the contract, unless otherwise directed. Teleconferences or additional face-to-face meetings may be more frequent at the request of the CO.

i) Gantt Chart

Within 10 calendar days of the effective date of the contract, the contractor shall submit a first draft of an updated Gantt Chart to the CO, CS and COR for review. The Gantt Chart shall be incorporated into the contract and will be used to monitor performance. The contractor shall include the key milestones, deliverables, and Go/No-Go decision gates.

j) Project Management Plan

In the management of this contract, the contractor is encouraged to utilize Project Management tools/techniques to track and monitor the cost and schedule of the project. The contractor and the government agree that at a minimum, the contractor shall utilize the cost and schedule tools/techniques in the contract deliverable for project management purposes.

k) Risk Management Plan

The contractor shall develop a high-level risk management plan within 30 days of contract award highlighting potential problems or issues that may arise during the life of the contract, including the impact on cost, schedule, and performance. Appropriate remediation plans. should reference relevant work segments where appropriate. Updates to this plan shall be included in the monthly Project Status Report.

l) Monthly and Annual Reports

If requested, the contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the SOW or other Project Management Plan tool(s):

- Executive summary highlighting the progress, issues, and relevant manufacturing, non-clinical, clinical, and regulatory activities.

- Progress in meeting contract deliverables, detailing the planned progress and actual

progress during the reporting period, explaining any differences between the two and corrective steps.

- Updated Risk Management Plan (when appropriate).
- One-month rolling forecast of planned activities.
- Progress of regulatory submissions.

m) Data Management

The contractor shall:

- Develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data.
- Provide for the statistical design and analysis of data resulting from the research.
- Provide raw data or specific analyses of data generated with contract funding to the CO, CS, and COR, upon request.

REGULATORY

The contractor shall perform the following as outlined below:

a) Engage the Food and Drug Administration (FDA) on a path to support the use of the product for the specific indication.

b) Prepare materials for and requesting, scheduling, and participating in all meetings with the FDA, including meetings to review all data packages.

c) Provide BARDA with (1) initial draft minutes and final draft minutes of any formal meeting with the FDA, and (2) final draft minutes of any informal meeting with the FDA.

FACILITIES, EQUIPMENT, & OTHER RESOURCES

The contractor shall provide equipment, facilities, and other resources required for implementation of the SOW to comply with all Federal and HHS regulations in:

a) The humane care and use of vertebrate animals.

b) The acquisition, handling, storage, and shipment of potentially dangerous biological and chemical agents, including select agents under biosafety levels required for working with the biological agents under study.

Attachment 3

Schedule of Payments

Pursuant to FAR 52.232-2, partial payments will be made upon receipt and acceptance of a deliverable and acceptable invoice for partial delivery of work, as outlined in the table below:

Partial Payment	Deliverable Title	Brief Description of Deliverable	Partial Payment Amount
1	Project Plan	Detailed project plan outlining the goals, deliverables, and intended pathway for the project. This plan should also include a Gantt Chart, Risk Management Plan, and indicate the tools/techniques used to track and monitor the cost and schedule of the project.	$25,000
2	EUA Submission to the FDA	Copy of DiaSorin EUA submission for a COVID serology assay and a copy of a letter or email from FDA acknowledging receipt	$100,000
~~3~~	~~EUA amendment to the FDA for expanded semiquantitative claim~~	~~Copy of DiaSorin EUA amendment submission for an expanded semiquantitative claim and a copy of a letter or email from FDA acknowledging receipt~~	~~$55,045~~
4	EUA submission for SARS CoV-2 IgM assay	Copy of DiaSorin EUA submission for a COVID IgM serology assay and a copy of a letter or email from FDA acknowledging receipt	$111,090
5	(1) Final Report; and (2) Final Data Package	(1) Final report to include a summation of the work performed and results obtained for the entire contract period of performance. (2) Final data package consisting of all raw data produced under this contract. Data may be used by DRIVe for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format.	There is no partial payment associated with the Final Report and Final Data Package.*

*The partial payment preceding the (1) Final Report and (2) Final Data Package (outlined in Section F of the contract) will not be paid until both the (1) Final Report and (2) Final Data Package are received and accepted by the Contracting Officer and Contracting Officer's Representative.